510(k) Summary
510(k) Number K123644

JAN 1 1 2013

Viztek, LLC.
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Jacksonville, FL 32217
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Date Prepared: November 9, 2012
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: ViZion + DR
   Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB,
   Common/Usual Name: Digital X-Ray Receptor Panel

2. **Equivalent legally marketed device**: Viztek ViZion DR, K112661 and Atlaim ATAL 8, K113812.

3. **Indications for Use (intended use)** ViZion + DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion + allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

4. **Description of the Device**: The ViZion + DR system represents the straightforward integration of a new digital x-ray receptor panel and our previously cleared software. This is a MODIFICATION of our clearance K112661 wherein we have changed the supplier of the panel.

   ViZion + DR is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) ViZion + is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of the Viztek PACS and the new receptor panel were not changed. Our main predicate is ViZion DR, K112661, wherein we combined our OPAL-RAD software with a new digital panel. We now also offer two sizes of panels: 14" x 17" and 17" x 17" panels.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates.

6. Substantial Equivalence Chart

Characteristic	Viztek ViZion DR K112661	Atlaim ATAL 8, K113812.	Viztek ViZion + DR
Intended Use:	ViZion DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	The ATAL 8 and ATAL 8c is indicated for use 'in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications	ViZion + DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion + allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.
Digital Panel	Samsung LTX240AA01-A (K090742) Pixel size 143 µm 3072 x 3072 pixels 9 million pixels.	Pixel size 139 µm 3072 X 3072 pixels (9 million pixels	iRay Technology (Shanghai) Ltd. For the 17" x 17" panel: Pixel size 139 µm 3064×3072 pixels (9 million pixels) For the 14" x 17" panel: Pixel size 150 µm 2288×2800 pixels (6.4 million pixels)
Software	Employs OPAL-RAD PACS image viewing and acquire interface software technology, K063337	The Atal-8 can be used with any FDA-cleared off-the-shelf radiographic image acquisition software package that outputs a suitable DICOM image like OmniVision software by OmniVision, cleared under K110040.	SAME as K112661, outputs a DICOM image.
DICOM	Yes	Option	Yes
Power source	AC Line	AC Line	AC Line
Electrical safety and EMC	Electrical Safety per IEC-60601. UL listed	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.

7. **Summary of Bench Testing Conducted:** IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility. MTF and DQE measurements, Risk Analysis and Software validation was conducted in accordance with FDA guidance documents.

8. **Summary of Clinical Testing:** Clinical images were acquired and evaluated by a board certified radiologist who concluded the images from the new panel are as good as or better than the images acquired with the predicate panel.

9. **Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Viztek Inc that the Viztek ViZion + DR is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 11, 2013

Viztek LLC
% Mr. Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

Re: K123644
Trade/Device Name: ViZion + DR. Digital Flat Panel X-Ray Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: MQB
Dated: November 15, 2012
Received: November 28, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123644

Device Name: ViZion + DR, Digital Flat Panel X-Ray Detector System

Indications For Use:
ViZion + DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion + allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

Prescription Use _X_ AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123644